OCT 1 8 2000

K000855

510(k) Premarket Notification, 2000
Günther Tulip Vena Cava MR*eye*™ Filter Set
COOK INCORPORATED

Safety and Effectiveness Information

Submitted By: Mary Gossard, M.S., Regulatory Affairs
COOK INCORPORATED
P.O. Box 489, 925 S. Curry Pike
Bloomington, In 47402
(812) 339-2235
March 15, 2000

Device:

Trade Name: Günther Tulip Vena Cava MR*eye*™Filter Set

Proposed Classification Name: Filter, Intravascular, Cardiovascular

Predicate Devices:

The Günther Tulip Vena Cava MR*eye*™Filter Set is similar in terms of intended use, materials of construction, and technological characteristics to the predicate devices reviewed, the Medi-tech (Boston Scientific) Stainless Steel *Greenfield* Vena Cava Filter and the Vena Tech (B. Braun Medical) *LGM-Vena Tech* 30 Series Filter.

Device Description

The Günther Tulip Vena Cava Filter is a cone-shaped wire filter fashioned of Elgiloy. The filter is non-magnetic and of conical shape with four legs. The end of each leg is slightly hooked outward. "Webbed" between the legs are tulip-shaped bent strands of the same alloy which maintain the shape of the filter by pressing outward toward the vein walls. These webs also increase the area into which the emboli can be trapped.

The filter set includes a needle, wire guide, dilator, introducer sheath and the introducer catheter. The implantation process utilizes the Seldinger technique and fluoroscopy to verify correct release and implantation location. Insertion can be made either through the jugular or the femoral vein. The jugular approach requires that the filter be loaded into the introducer before implantation. The femoral approach filter is preloaded. The device is supplied sterile and is intended for one time use.

Substantial Equivalence

Devices manufactured and distributed by Boston Scientific (Medi-tech), the Stainless Steel *Greenfield Vena Cava Filter*, and B. Braun Medical (Vena Tech), the *LGM-Vena Tech* 30 Series are believed to be substantially equivalent to the COOK *Günther Tulip Filter*, subject of this submission. The similar indications for use and technological characteristics of the GTF and the predicate devices support a determination of substantial equivalency.

Test Data

The Günther Tulip Vena Cava MR*eye*™ Filter Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests were comprised of:

- Clinical Experience
- Material and Stress Analysis Tests
- Biocompatibility Tests

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as an inferior vena cava filter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2000

Ms. Mary A. Gossard, M.S.
Regulatory Affairs Coordinator
COOK Incorporated
P.O. Box 489
925 S. Curry Pike
Bloomington, IN 47402

Re: K000855
Trade Name: Günther Tulip Vena Cava MReye™ Filter Set
Regulatory Class: II (two)
Product Code: DTK
Dated: September 29, 2000
Received: October 2, 2000

Dear Ms. Gossard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K000855

Device Name: Günther Tulip Vena Cava MR*eye*™ Filter Set

Indications for Use:
The Günther Tulip Vena Cava MR*eye*™ Filter Set (GTF) is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- pulmonary thromboembolism when anticoagulation therapy is contraindicated;
- failure of anticoagulation therapy in thromboembolic diseases;
- emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- chronic, recurrent pulmonary embolism where anticoagulation therapy has failed or is contraindicated.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K000855

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use____
(Per 21 CFR 801.109)